

In accordance with the discussion had at the Interview extended undersigned counsel, Applicant discussed, among other things, the prior art with the Examiner. In that discussion, the Applicant advised the Examiner that Applicant's invention resides in the discovery that it is exposure to NOx fumes that results in the formation of elevated levels of Tobacco Specific Nitrosoamines (TSNAa) in cured tobacco. In particular, Applicant emphasizes that prior to his discovery, cured tobacco was made in this country with relatively low TSNA levels, through the fortuitous use of a heating element other than a direct fire heating unit. However, Applicant is the first to discover there is a direct correlation between NOx exposure and TSNA formation.

Applicant has amended the claims previously examined to emphasize that the invention is based on the observation by the inventor that there is a correlation between the level of nitric oxides to which tobacco being cured in a barn is exposed, and the tobacco-specific nitrosamines found in the tobacco upon curing. As noted in the Interview Summary "the Examiner agrees with Applicant's assertion that the prior art of record does not appear to teach or suggest a correlation between the NOx and TSNA levels in tobacco." Claim 1 stresses this aspect of the invention, in noting that the barn is modified to permit correlation between NOx levels and TSNA levels in the cured tobacco. Consistent with the discussion had at the Interview, Claims 2-4 have been cancelled. Additionally, Claims 8-13, originally restricted out, have been cancelled.

During prosecution, Applicant added by amendment Claims 14-58. Those claims have been cancelled, and will be introduced in pending continuation application 10/223,752.

The positive steps of new independent Claim 59 find direct counterparts in original Claim 1. Applicant has specifically recited in Claim 59 that which was implicit in Claim 1, that is, that the barn modification permits correlation between NOx levels and TSNA levels. As discussed with Examiner Walls, correlating NOx and TSNA levels is taught specifically by the Examples, see the first paragraph of page 15 (Example 1), the paragraph bridging pages 15 and

16 (Example 2), and the longer paragraph bridging pages 16-17. In each case, higher NOx levels are correlated with higher TSNA levels, whereas in barns that are modified to control NOx levels, reduced nitric oxide levels are correlated with lower TSNA levels. See also, page 4, lines 18-28.

As the amendments to the claims do not introduce new matter, simplify the case for consideration, and cancel claims withdrawn from consideration, entry and consideration are respectfully requested. Upon entry, Claims 1, 5-7, and 59 remain pending in the case.

REQUEST FOR RECONSIDERATION

Applicant requests reconsideration of the rejection of Claims 1-7 as obvious over a combination of Fowler (USP 4,206,554) taken in view of Bullock (USP 5,018,281) and O'Donnell, Jr. (USP 5,803,081). See, Paper No. 3, pages 3-5.

As was discussed with the Examiner, in addition to the teachings of O'Donnell, column 2, lines 12-38, which teach the formation of TSNA's on curing, without identifying a cause for the same, the status of the art is that there were tobacco curing barns in the United States, more than a year in advance of the effective filing date of the above-captioned application, where cured tobacco of low TSNA levels was obtained. For example, the assignee of the present application has data collected in 1996, as well in other years, that confirm that prior art indirect fired barns provide cured tobacco with very low and even undetectable TSNA levels. The observations of the assignee are confirmed in the letter to attorney Delmendo from Harold Burton dated August 28, 1998, submitted herewith, bearing Bates No. BAW-017916. Applicant recognizes that this letter carries the legend "CONFIDENTIAL SUBJECT TO PROTECTIVE ORDER IN STAR v.

RJR,” which litigation is discussed below, but advises the Office that confidentiality restrictions as to this letter no longer apply. Specifically, Reynolds’ litigation counsel wrote to Star’s litigation counsel on December 20, 2002 and requested that the confidentiality restriction be lifted. Star’s litigation counsel did not respond to Reynolds’ request or otherwise file a motion seeking to preserve the confidentiality of the document within the 21-day period proscribed by the Protective Order in that litigation. As a result, the confidentiality restriction was automatically removed by operation of the Order effective January 11, 2003. In the letter, Burton observes that technology used in the United States during the “60s” (1960s), currently used in China, inherently gives rise to low TSNA-content tobacco. This was achieved by curing using radiant heating.

Against this background, the claims of Applicant are clearly directed to patentable subject matter. Applicant is not claiming low TSNA tobacco, or even a general method for curing tobacco to give low TSNA values. Rather, Applicant’s recognition of the correlation between NOx and TSNA levels gives basis for modifying the barns currently used in America to provide a curing environment that does not bring NOx gases into contact with the tobacco leaves, which can be correlated with a low TSNA level. As discussed, Applicant’s recognition is nowhere foretold in the art.

Turning to the specific references relied on by the Examiner, as noted above, while O’Donnell does observe that TSNA formation is associated with curing (*the curing process itself must be responsible for production of the harmful carcinogenic nitrosamines*), O’Donnell does not link TSNA formations to NOx exposure, or otherwise provide one of ordinary skill in the art information on how to modify direct fire barns, as claimed herein, so as to avoid NOx content, and thereby produce cured tobacco with low TSNA levels. Indeed, the O’Donnell teaching is quite the opposite, since curing, according to O’Donnell, necessarily introduces TSNA’s,

O'Donnell looks for an alternative which permits the use of uncured or "green" tobacco. ('081 patent, column 6, lines 5-22.), or treating the uncured "yellow" tobacco with microwaves or flash convection heating to kill the microbes O'Donnell thought to be responsible for the formation of nitrosamines. (Id at col. 7, lines 10-20). Even in a simple comparison, Applicant's claims, as amended, define over the art assembled. Applicant further notes that the Examiner's reliance on the combination of Fowler and Bullock to suggest replacing direct fire heaters may be misplaced. Specifically, the discussion of the electric cost in Bullock appears to be directed to the cost of maintaining the fan system, and air flow distribution, and not heating itself. The same is true of Fowler, which, although describing a heat exchange method, does not specifically identify the heating source, and is consistent with the use of a direct fire method. Fundamentally, Applicant's claims are directed to an invention not only not taught by the art relied on, as acknowledged by the Examiner, but also to the extent it is addressed, is taught away from, in that O'Donnell comes to the conclusion that curing, independent of the conditions used, will lead to the formation of TSNA's. It is Applicant who has discovered the correlation between TSNA levels and NOx levels, nowhere recognized in the art.

PENDING LITIGATION

As discussed during the afore-referenced Interview, although not directly related to the prosecution of the above-captioned application, the Examiner is advised that the real-party-in-interest and assignee of the entire right, title, and interest, to the above-captioned application, R.J. Reynolds Tobacco, Inc., has been sued by Star Scientific, alleging infringement under U.S. Patents 6,202,649 and 4,364,401. In connection with that litigation, the plaintiff, Star, has asserted that NOx from combustion exhaust gases is not the cause for TSNA's in flue-cured tobacco. While this would nominally appear to be contradictory to Applicant's discovery, further

reinforcing Applicant's invention, Applicant also advises that, prior to its litigation with Reynolds, Star acknowledged in the Patent Office that Applicant's theory is correct. Dr. Burton, Star's technical consultant, and the author of the letter discussed above, acknowledged in the prosecution of USSN 08/998,043 in a Declaration submitted herewith, bearing Deposition Exhibit No. 67, that it is in fact the reaction of the combustion products of direct-fired heating with components in the tobacco that leads to the formation of TSNA. Burton sets this forth at paragraph 16 of the Declaration.

Marley (US Patent 4,790,335) relies solely on direct-fired heating to obtain the desired temperatures. The use of direct-fired heating actually contributes to the formation of nitrosamines. Combustion products react with components in the tobacco leaf to form nitrosamines.

Burton's Declaration is dated March 27, 2000, and therefore not prior art with respect to Applicant. In addition, in an Amendment and Response accompanying Dr. Burton's declaration, Star stated:

Here, nothing in Marley teaches or even remotely suggests curing tobacco under conditions suitable to obtain any tobacco product having a reduced NNK content as claimed herein. For example, the Marley arrangement does nothing to prevent combustion exhaust gases from entering the curing chamber during drying of tobacco. The presence of combustion exhaust gases, which contain nitrogen oxides, actually contribute to the formation of NNK and other nitrosamines in tobacco. (See Burton Declaration ¶ 16)

Star repeated the above statement and again acknowledged that Applicant's theory was correct when it submitted a copy of Dr. Buton's declaration in another pending application, serial no. 08/879,905. On deposition, Burton reconfirmed the accuracy of Applicant Peele's observation that TSNA formation is linked to exposure to exhaust gases. Burton's deposition was taken June 26, 2002, in the referenced litigation (United States District Court, District of Maryland, Southern Division (AW-01-CV-1504)). The following exchange occurred in discussing Burton's Declaration.

Q. You say Marley, and that's one of the patents –

A. Marley, yeah.

Q. Cited by the Examiner - relies solely on direct-fired heat to obtain the desired temperatures. The use of direct-fired heating actually contributes to the formation of nitrosamines. Combustion products react with components in the tobacco leaf to form nitrosamines. You see that?

A. Yes.

Q. Is that a correct statement?

A. Yes.

Q. And that was correct when you made it, and it's still correct today as far as you're concerned?

A. Yes.

Q. And when you say combustion products react with components in tobacco to form nitrosamines, what was the basis for your statement that you made to the Patent Office? How did you reach that conclusion?

A. I do not know.

Q. In fact, sir, you had reached that conclusion based on information you had obtained from the presentation that Reynolds (assignee of the above-captioned application) had given on the mechanism for the formation of TSNAs in flue-cured tobacco; isn't that correct?

A. I really don't know.

Q. And when you say the combustion products react with the components in the tobacco leaf they form nitrosamines, what do you mean by that? I mean, you're not referring to microbial action in that statement, are you?

A. No.

Q. It's the actual components in the combustion exhaust gases reacting directly with the alkaloids in the tobacco. Correct?

A. Yes.

Transcript of the Deposition of Harold Burton, Ph.D., taken June 26, 2002, page 92, line 15 -
page 94, line 1.

Thus, notwithstanding its litigation stance, Star previously acknowledged that the NOx component of combustion exhaust gases contribute to the formation of TSNA's, a discovery first identified by Applicant herein. Applicant's claimed modification therefore is a valuable modification that removes this cause of TSNA formation from curing barns and correlates the tobacco-specific nitrosamine content of the cured tobacco with the actual level of nitric oxides to which the tobacco is exposed in the barn ..

IDS

During discussions with the Examiner, the Examiner noted that Applicant's IDS of July, 2002, included two references, Nos. 127 and 150, that did not include dates of public availability. Applicant confirms that Reference 127, from Powell Mfg. Co., Inc., is believed to have been publically available in the late 1970s, and in any event, no later than January 1980. Applicant continues to endeavor to find a certain date for Reference 150, and has been unable to up to this time to identify a date of availability earlier than May 15, 2000, which is consistent with the title of the reference. The reference thus appears to have a date of availability after applicants own filing date, and serves only to establish the general level of understanding in the art.

The specification has been amended to correctly reflect the continuation parentage. The claims have been amended to confine the claims to subject matter not withdrawn from examination, and present it in such a way to identify patentable subject matter, subject matter that there is general agreement Applicant was first to invent. As the claims otherwise conform to the requirements of Title 35, they are believed in condition for allowance. An early and favorable action thereon is respectfully requested. In the event the Examiner has any remaining questions regarding the case, she is invited to contact undersigned counsel at 202-861-6675.

Respectfully submitted,

PIPER RUDNICK LLP



Steven B. Kelber
Registration No. 30,073
Attorney of Record

1200 Nineteenth Street, N.W.
Washington, D.C. 20036-2412
Telephone No. (202) 861-3900
Facsimile No. (202) 223-2085

SERIAL NO. 09/735,177

DOCKET NO.: 3843-002-27 CONT

MARKED-UP COPY OF AMENDED CLAIMS

5. (Amended) The method of Claim [1] 59 whereby nitric oxide levels within the barn during curing approximate that of ambient, environmental air surrounding the barn.

6. (Amended) The method of Claim [1] 59 whereby the barn is equipped with a heat exchange unit.

7. (Amended) The method of Claim [1] 59 whereby the barn is equipped with an electrical heating unit.